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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,489	09/17/2002	Travis Robert Glare	24747-1104US	6955
35489	7590	12/23/2005	EXAMINER	
HELLER EHRMAN LLP			KUBELIK, ANNE R	
275 MIDDLEFIELD ROAD			ART UNIT	
MENLO PARK, CA 94025-3506			PAPER NUMBER	

1638

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,489

Applicant(s)

GLARE ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005 and 12 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 17-40 and 44-65 is/are pending in the application.
- 4a) Of the above claim(s) 15, 17-40 and 44-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 15, 17-40 and 44-65 are pending.
2. This application contains claims 15, 17-40 and 44-48 drawn to an invention nonelected with traverse in the response filed 15 November 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The objection to claims 2-4 and 10 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is obviated by their cancellation.
5. The objection to claims 14, 16 and 41 because of informalities is obviated by their cancellation.
6. The rejection, as it would apply to the new claim 57, of claim 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of new claim 57 indicating that it is an additional nucleic acid that encodes the proteins.
7. The rejection, as it would apply to the instant claims, of claims 1-14, 16 and 41-43 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.
8. The rejection, as it would apply to the instant claims, of claims 1, 9-10, 12-14, 16 and 41 under 35 U.S.C. 102(e) as being anticipated by Kramer et al (US Patent 6,281,413, filed February 1998) is withdrawn in light of Applicant's amendment of the claims.

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9. The rejection, as it would apply to the instant claims, of claims 1, 9-10 and 12-14 under 35 U.S.C. 102(b) as being anticipated by Jarrett et al (WO 98/08388) is withdrawn in light of Applicant's amendment of the claims.

Claim Objections

10. Claim 65 is objected to because it has an improper article before "nucleic" in line 1.

11. Claim 63 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Parent claim 60 is drawn to a recombinant expression vector comprising a nucleic acid of claims 49-51. Claim 63 is drawn to a vector wherein the vector is pUC19, pProEX HT, pBR322, pACYC184 or pLAFR3. None of these vectors comprise the nucleic acid of claims 49, 50 or 51. This claim 63 fails to further limit the parent claim.

Claim Rejections - 35 USC § 112

12. Claims 50-51 and 56-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 February 2005, as applied to claims 1, 9-14, 16 and 41. Applicant's arguments filed 2 June 2005 have been fully considered but they are not persuasive.

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Applicant urges that one of skill in the art would be able to identify a nucleic acid with 70% homology to SEQ ID NO:1 and assay the activity of the encoded protein (response pg 15).

This is not found persuasive. Applicant's arguments are drawn to an enablement rejection and will be addressed below. The specification fails to describe the necessary and sufficient structural elements that distinguish nucleic acid with 70% homology to SEQ ID NO:1 and that encode pesticidal proteins from nucleic acid with 70% homology to SEQ ID NO:1 and that do not encode pesticidal proteins.

13. Claims 50-52 and 55-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO:1, and a method of expressing SEQ ID NOs:2-4 in *E.coli*, does not reasonably provide enablement for nucleic acids that have 70% homology to SEQ ID NO:1, a recombinant expression vector comprising the nucleic acid, a method of producing the protein encoding by the nucleic acid and a plant, bacterium, virus or fungus transformed with the nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 February 2005, as applied to claims 1, 9-14, 16 and 41. Applicant's arguments filed 2 June 2005 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art would be able to identify a nucleic acid with 70% homology to SEQ ID NO:1 and assay the activity of the encoded protein (response pg 15 and 16).

This is not found persuasive. SEQ ID NO:1 is 18937 nucleotides long and a nucleic acid with 70% identity to it would have 5681 nucleotide substitutions relative to SEQ ID NO:1. As

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the total number of amino acids of all the proteins encoded by SEQ ID NO:1 is 4776, this means that the claimed nucleic acid encompasses nucleic acids in which every single amino acid of all the encoded proteins is substituted. The specification does not teach how to substitute every amino acid of the encoded protein. Without guidance, making all these substitutions and assaying the encoded protein would require undue trial and error experimentation.

Applicant urges that one of skill in the art would be able to make the transformed plants, bacteria, viruses, fungi and vectors using standard techniques (response pg 16).

This is not found persuasive. The claims drawn transformed plants, bacteria, viruses, fungi and vectors are rejected because the specification doesn't teach how to make the nucleic acids required to make the transformed plants, bacteria, viruses, fungi and vectors, not for making transformed plants, bacteria, viruses, fungi and vectors, per se.

Applicant urges that hybridization techniques are well-known in the art, citing Sambrook (response pg 16).

This is not found persuasive, but this portion of the rejection is moot as the instant claims are not drawn tot hybridization. Sambrook could not be considered because it was not sent.

Applicant urges that new claim 50 has a functional limitation and the specification teaches how to assay the protein (response pg 17).

This is not found persuasive. SEQ ID NO:1 is 18937 nucleotides long and a nucleic acid with 70% identity to it would have 5681 nucleotide substitutions relative to SEQ ID NO:1. As the total number of amino acids of all the proteins encoded by SEQ ID NO:1 is 4776, this means that the claimed nucleic acid encompasses nucleic acids in which every single amino acid of all the encoded proteins is substituted. The specification does not teach how to substitute every

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amino acid of the encoded protein. Without guidance, making all these substitutions and assaying the encoded protein would require undue trial and error experimentation.

The claims are also drawn to nucleic acids that encode only one of SEQ ID NOs:2-4. The specification teaches that mutations in the coding regions for any one of SEQ ID NOs:2-4 eliminate the disease causing ability of all of SEQ ID NO:1 (pg 25, lines 11-14; Fig. 2c). Thus, none of SEQ ID NO:2-4 alone are sufficient to provide resistance to *Costelytra zealandica* larvae, and a plant transformed with a nucleic acid encoding only one or two would not be resistant. Additionally, nucleic acids encoding only SEQ ID NO:2 (SepA) could not be expressed in bacteria (Hurst et al, 2000, J. Bacteriol. 182:5127-5138; see paragraph spanning pg 5133-5134 and that spanning the columns on pg 5134). Furthermore, the specification does not teach how a use a nucleic acid encoding only one of SEQ ID NOs:2-4.

Claim Rejections - 35 USC § 112

14. Claim 63 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 63 lacks antecedent basis for the limitation “the recombinant expression vector of claim 62” as claim 62 is drawn to a host.

Claim Rejections - 35 USC § 102

15. Claims 49-56 and 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Grkovic et al (1995, Appl. Environ. Microbiol. 61:2218-2223) taken with the evidence of the instant application. The rejection is repeated for the reasons of record as set forth in the Office

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action mailed 11 February 2005, as applied to claims 1-4, 7 and 9-11. Applicant's arguments filed 2 June 2005 have been fully considered but they are not persuasive.

Applicant urges that Grkovic et al only describes a plasmid clone with only one partial disease conferring region and did not teach the sequence of this clone (response pg 18).

This is not found persuasive. The instant specification teaches pADAP comprises SEQ ID NO:1 (pg 23-26 and Table 1). SEQ ID NO:1 is an inherent property of pADAP.

16. Claim 63 is rejected under 35 U.S.C. 102(b) as being anticipated by Rose (1988, Nucleic Acids Res. 16:355).

Rose teaches pACYC184.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

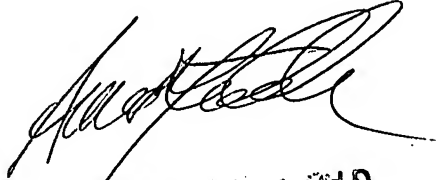
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Anne Kubelik, Ph.D.
December 8, 2005



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER